Claims

1. A stable pharmaceutical composition of erythropoietin (EPO), wherein the composition comprises:

a. a therapeutically effective amount of EPO,

b. a pharmaceutically acceptable pH buffering system,

c. a poloxamer polyol, and

d. a polyhydric alcohol.

2. The composition according to claim 1, wherein the composition is free of additives derived from human and/or animal origin.

3. The composition according to claim 1 or 2, wherein the composition optionally further comprises:

e. an isotonifying agent and/or

f. one or more pharmaceutically acceptable excipient(s).

4. The composition of any one of claims 1 to 3, wherein the composition is aqueous.

5. The composition of any one of claims 1 to 4, wherein the pharmaceutical quantity of EPO is formulated to provide a quantity per dose in the range of about 500 to about 100000 IU EPO.

6. The composition of claim 5, wherein the pharmaceutical quantity is formulated to provide a quantity per dose selected from the group consisting of about 1000 IU, about 2000IU, about 3000 IU, about 4000 IU, about 10000 IU, about 20000 IU, about 25000 IU, about 40000 IU, about 50000 IU, about 60000 IU and about 100000 IU.

7. The composition of any one of claims 1 to 6, wherein the pH buffering system provides a pH range from about 6 to about 8.

8. The composition of claim 7, wherein the pH buffering system provides a pH range from about 6.8 to about 7.5.

9. The composition of claim 7, wherein the pH buffering system provides a pH of about 7.0.

10. The composition of any one of claims 1 to 9, wherein the pH buffering system is phosphate buffer.

11. The composition of any one of claims 1 to 10, wherein the poloxamer polyol is selected from the group of non-ionic surface active agents

12. The composition of claim 11, wherein the poloxamer polyol is Pluronic F68.
13. The composition of claim 11, wherein the poloxamer polyol is comprised in a range of about 0.05% to about 0.5%.
14. The composition of claim 11, wherein the concentration of poloxamer polyol is about 0.1%.
15. The composition of any one of claims 1 to 14, wherein the polyhydric alcohol is selected from the group comprising glycerol, sorbitol, mannitol and/or xyliol.
16. The composition of claim 15, wherein the polyhydric alcohol is glycerol.
17. The composition of claim 15, wherein the concentration of polyhydric alcohol is in the range of about 0.1% to about 10%.
18. The composition of claim 15, wherein the concentration of polyhydric alcohol is in the range of about 2% to about 5%.
19. The composition of any one of claims 1 to 18, wherein said isotonifying agent is selected from the group consisting of inorganic salts.
20. The composition of claim 19, wherein said isotonifying agent is NaCl.
21. A process for preparing a composition containing erythropoietin (EPO), comprising mixing of EPO with a poloxamer polyol and a polyhidric alcohol, wherein the composition of any of claims of 1 to 20 is prepared.
22. Use of a composition of any one of claims 1 to 20 for the preparation of a medicament for the treatment and/or prevention of diseases selected from anemia of malignant disease, i.e. any type of solid cancer, or haematological cancer including leukaemia, lymphoma and multiple myeloma, anemia resulting from a chemotherapeutic/radiation treatment of a malignant disease, anemia of chronic disease including for example autoimmune diseases such as rheumatoid arthritis and hepatitis, anemia in AIDS patients, especially those treated with AZT, anemia of prematurity, anemia associated with (chronic) renal failure, anemia of thalasemia, autoimmune haemolytic anemia, aplastic anemia, and anemia associated with surgery, the treatment of fatigue, pain, chronic heart failure, dysrythmia or dementia, preoperatively use to reduce the need for allogenic blood transfusion in non-vascular and non-cardiac surgery.